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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,421	05/17/2006	Jan Clair Nielsen	NIELSEN6A	5536

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EXAMINER	
GANGLE, BRIAN J	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/562,421	NIELSEN, JAN CLAIR	
	Examiner	Art Unit	
	Brian J. Gangle	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *See Continuation Sheet* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1,2,4-8,11,15-26,29,31,32,34,35,37,38,40-43,45,48-52,55,58,59,63-66,68,70-76,79-82,84,86-88,90-95 and 98-110.

Continuation of Disposition of Claims: Claims rejected are 1,2,4-8,11,15-26,29,31,32,34,35,37,38,40-43,45,48-52,55,58,59,63-66,68,70-76,79-82,84,86-88,90-95 and 98-110.

DETAILED ACTION

Applicant's petition under 37 CFR 1.103(a), filed on 11/25/2009, has been considered. The petition is DISMISSED because applicant has shown insufficient cause for suspension.

Applicant's amendment and remarks, filed on 5/4/2009 and 11/5/2009, are acknowledged. With the entry of the latest amendment, claims 1-2, 4, 5, 6-8, 11, 15-26, 29, 31-32, 34-35, 37-38, 40-43, 45, 48-52, 55, 58-59, 63-66, 68, 70-76, 79-82, 84, 86-88, 90-95, and 98-110 are pending and are currently under examination.

Objections Withdrawn

The objection to the drawings, as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: Figures 11-14, is withdrawn in light of applicant's amendment to the specification.

The objection to claim 1 because each claim should end with a period, is withdrawn in light of applicant's amendment thereto.

Objections Maintained

The objection to the specification for the use of trademarks is maintained.

Trademarks should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Applicant's amendment to correct the use of the trademark, TWEEN, is noted. However, applicant has not corrected other trademarks found in the application in numerous places. For example, the trademark LALLEMAND is found on page 37, VINIFLORA is found on page 46-47 and 50, and OXOID is found on pages 42-45 and 47.

It is noted that the cited occurrences of improper use are only exemplary and applicant should review the specification to correct any other use of trademarks.

New Claim Objections

Claim 65 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The microbial organism is required by claim 1 to be capable of fermenting malic acid to lactic acid.

Claim Rejections Withdrawn

The rejection of claim 15 under 35 U.S.C.§112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention (biological deposit rejection), is withdrawn in light of applicant's remarks regarding the availability of the biological deposit.

The rejection of claims 4 and 6-7, under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn in light of applicant's amendment thereto.

The rejection of claims 13-15, under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is withdrawn. Claims 13-14 have been cancelled, thus the rejection of these claims is moot. The rejection of claim 15 is withdrawn in light of applicant's amendment to claim 1 and remarks.

Claim Rejections Maintained

35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 4, 6-8, 11, 16, 18-20, 22-26, 29, 31-32, 34-35, 37-38, 40-43, 45, 48-49, 55, 58-59, 63-66, 70-76, 79-82, 86-88, 90-95, and 98-110 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons set forth in the rejection of claims 1-2, 4, 6-9, 11, 13-15, 43, 45, and 48-49 in the previous office action. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant argues:

1. That the examiner's position that, since applicant has not characterized the genetic nature of the mutations in the parent strain, applicant should be limited to the deposited strains, is incorrect. Applicant argues that, if this view of the written description requirement were to prevail, patents on novel organisms obtained by random mutation and selection, or spontaneous mutants isolated from nature would be commercially worthless, as protection limited to the deposited strain would be easily evaded as competitors could order the deposited strains shipped to a location outside the US, mutate it there, then use the mutated strain in the US with impunity. Applicant also argues that competitors could also make mutants of a non-infringing strain in the US and screen for mutants with the same functionality using the disclosed screening assay. Applicant's argue that inventors would then keep such organisms as trade secrets rather than enriching the art by depositing the organisms and describing their characteristics.

2. That the examiner cites Eli Lilly, Amgen, and Fiddes as basis for requiring disclosure of the sequence of a nucleic acid or protein. Applicant argues that these cases are related to claims to nucleic acids or proteins and that the instant claims are to organisms of a class which performs malolactic fermentation. Applicant also argues that these cases do not require that every invention be described in the same way and that the PTO has been granting patents on new microorganisms since well before DNA sequencing methods were developed (and thus before there was knowledge of specific sequence-activity correlations).

3. That applicant agrees that the metabolic characteristics of the deposited organisms are the result of mutation of the genes of those organisms, but that it does not follow that a claim to a mutated organism is subject to the written description standard which *Eli Lilly* developed for claims to nucleic acids. Applicant also refers to *Fiers*, where the court emphasized not merely

that the count was to a product, but that it was a chemical and it characterized DNA as being a complex chemical. Applicant argues that an organism is not merely a chemical.

4. That applicant's disclosure is of more than merely a desired function for the organisms. Applicant states that they have deposited three strains that have the desired function and that in *Enzo*, the court held that the deposited *Neisseria* inherently described the claimed probes because the inserts could have been recovered and sequenced. Applicant argues that, like the patentees in *Enzo*, they have deposited the strains and the art could compare the differences between the genomes of DSM 15569, 15570, and 15571 with a reference strain.

5. That the PTO has failed to make a showing that it is rare for a radiation or chemically-induced mutant of *Oenococcus oeni* to possess the claimed trait of reduced citric acid-degradative activity. Applicant argues that it may be that applicants were the first to recognize that such mutants could be made and to provide an assay for identifying them. Applicant argues that if the mutations conferring such functionality are not rare within the taxon of interest, it follows that the three disclosed mutants are representative of the broader genus.

Applicant's arguments have been fully considered and deemed non-persuasive.

Regarding argument 1, applicant's opinion on the utility of the patent system and the ways to skirt patent protection are interesting; however, they are an argument with regard to whether there should be a written description requirement and are not relevant to whether or not the written description requirement has been met. It is of note that applicant's means of skirting patent protection (taking strains owned by another and mutating them in order to obtain their own strain) is precisely the manner in which applicant discloses to obtain the current invention.

Regarding argument 2, applicant correctly points out that the cited cases are related to claims drawn to nucleic acids or proteins and that the PTO has been granting patents on microorganisms since before DNA sequencing methods were developed. Whether or not the PTO has issued cases to microorganisms in the past is not relevant to the instant case, as it is the laws that are currently in place that govern the instant case. While the cited cases are directly related to nucleic acids and proteins, the legal principles discussed are not limited to nucleic acids and proteins. Furthermore, while applicant is claiming an organism, the fact is that the claimed characteristics of said organism are obtained through mutation of known organisms. Applicant is taking known and disclosed bacteria and altering their nucleic acids so that said

bacteria will have new characteristics. It is the structure of these nucleic acids that leads to the claimed functions. Therefore, the principles discussed in the cited cases are relevant to the instant case. With the exception of the deposited organisms, which are described not by any structural information, but rather only by virtue of the biological deposit, applicant has described their invention using functional characteristics alone. These characteristics have not been correlated in any way to any known structure. As set forth by the courts, functional description alone is insufficient to satisfy the written description requirement. In *Fiers* , 984 F.2d at 1169-71, 25 USPQ2d at 1605-06, the court stated "The present count is to a product, a DNA which codes for b-IF; it is a claim to a product having a particular biological activity or function, and in *Amgen,* we held that such a product is not conceived until one can define it other than by its biological activity or function." While the case was specifically dealing with DNA, the court stated that a *product* is not conceived until one can define it by other than it's biological activity or function.

Regarding argument 3, applicant is correct that an organism is not merely a chemical. Instead, an organism is a very complex collection of chemicals. The functional, metabolic characteristics of an organism are directly related to the nature of those chemicals (particularly DNA) and the chemical reactions that occur due to the nature of those chemicals. Since the mutations of the chemicals in the organisms (i.e. DNA) is what directly leads to the claimed characteristics (as agreed by applicant), it is the nature of those mutations that is important and, as stated above, the principles set forth in *Eli Lilly* and *Fiers* are applicable to the instant case.

Regarding argument 4, applicant is correct in citing *Enzo* as applicable to the instant rejection; however, applicant's interpretation of *Enzo* leaves out the most important points. First, the court did NOT hold that the deposited *Neisseria* inherently described the claimed probes because the inserts could have been recovered and sequenced. The court did hold that "reference in the specification to a deposit in a public depository, which makes its contents accessible to the public when it is not otherwise available in written form, constitutes an adequate description of the deposited material sufficient to comply with the written description requirement of § 112, ¶ 1." This is entirely consistent with the instant rejection and is not at all what applicant makes it out to be. The court stated that a deposit constitutes an adequate description *of the deposited material* sufficient to comply with the written description requirement. As applicant has already

noted, the examiner considers the deposited strains to meet the written description requirements. What applicant has left out of their interpretation of *Enzo* is that the claims encompassed far more than the deposited material. The court expressly declined to rule that the claims met the written description requirements because of the broad subject matter of the claims (beyond the deposited material). It is this broader subject matter that is the subject of the instant invention. The *Enzo* court did state that not all functional descriptions of genetic material fail to meet the written description requirement, affirming the PTO guidelines and stating "under the Guidelines, the written description requirement would be met for all of the claims of the '659 patent if the functional characteristic of preferential binding to *N. gonorrhoeae* over *N. meningitidis* were coupled with a disclosed correlation between that function and a structure that is sufficiently known or disclosed." It is precisely this disclosed correlation between the function and structure that is lacking from the instant specification.

Regarding argument 5, since the art has not shown whether this is the case and applicant has not shown this is the case, then it is quite clear that there is neither an art-recognized correlation nor a disclosed correlation between the structure and function of the claimed organisms. Applicant has not described, in any way, the mutations that lead to the required function.

Applicant has agreed that the strains DSM 15569, 15570, and 15571 are the only strains described as meeting the limitations of the claims. Applicant has not described any other microbial organism which does so, but has instead described a method for obtaining other strains which meet the limitations. As the strains were obtained by randomly mutating known organisms and selecting those organisms with the desired characteristics, there is no predictable relationship between the strains DSM 15569, 15570, and 15571 and any other organism.

As outlined previously, the instant claims are drawn to an isolated and purified microbial organism that is capable of fermenting malic acid to lactic acid, and which, when placed in a medium containing 1-5000 mg/L of citric acid is only capable of degrading at the most 80% or said citric acid. Said organisms must be capable, under suitable conditions, of adaptation to, when said microbial organism in a frozen or freeze dried state is added directly into a fermented fruit juice: i) a survival rate which is at least 1% after two days at 23° C in a fermented sterile fruit juice with a pH of less than 4 and comprising at least 12 vol % ethanol; ii) a survival rate

which is at least 70% after two days at 17° C in a fermented sterile fruit juice with a pH of less than 4 comprising at least 13.9 vol % ethanol.

The specification discloses a list of bacteria that can be mutagenized and then selected in order to obtain a strain that meets the limitations of the claims. Strains DSM 15569, 15570, and 15571 are described as meeting the limitations of the claims. Applicant has not described any other microbial organism which does so. However, there is no correlation between the required function (i.e. the required characteristics) and the structure of the product (the microbial organism). Applicant has not described what organisms would have the characteristics required by the claims.

Therefore, the specification provides insufficient written description to support the genus encompassed by the claim. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that

"applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid and/or protein itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404. 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and does so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines Inc. , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2datl966.

All applicant has provided in the specification is a means for isolating the organism of the claims, and there is no description of an actual organism that meets the limitations (with the exception of strains DSM 15569, 15570, and 15571). Because possession of the invention, rather than a means for obtaining it is required, the claims do not meet the written description requirements.

Therefore, applicant has not demonstrated possession of the claimed genus of microbial organisms and has not shown any organism (with the exception of strains DSM 15569, 15570, and 15571) that meets the limitations of the claims.

With regard to claims 66 and 82, the claims require a microbial organism that is in the *Oenococcus* family or the *Lactobacillus* family. Applicant has not described any such organisms because no such family designations exist.

New Claim Rejections

35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 4, 5, 6-8, 11, 15-26, 29, 31-32, 34-35, 37-38, 40-43, 45, 48-52, 55, 58-59, 63-66, 68, 70-76, 79-82, 84, 86-88, 90-95, and 98-110 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicant has amended claim 1 to recite "within the period required for essentially complete degradation of the malic acid within the medium." This phrase does not appear in the specification or original claims as filed. Applicant does not point out specific basis for this limitation in the application, and none is apparent. Therefore, this limitation is new matter.

Applicant has added new claim 105 which recites "wherein the organism is selected from the group consisting of DSM15569, DSM15570, DSM15571, and mutants derived directly or

indirectly therefrom." Applicant points to pages 19, 26, and 27 to provide support for this new claim. However, there is no mention of mutants (either direct or indirect) of these particular strains in these pages. Therefore, this limitation is new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2, 4, 5, 6-8, 11, 15-26, 29, 31-32, 34-35, 37-38, 40-43, 45, 48-52, 55, 58-59, 63-66, 68, 70-76, 79-82, 84, 86-88, 90-95, and 98-110 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered vague and indefinite by the phrase "essentially complete degradation of the malic acid within the medium." The term "essentially" is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 34 recites the limitation "said grape juice" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 50 is vague and indefinite because the recited method steps do not correlate to the stated goal of the claim and are thus inconsistent with the preamble of the claim. Claim 1 requires a microbial organism that has a specified set of functional characteristics. The method steps of claim 50 would not lead to production of such an organism. For example, claim 50 requires isolation of an organism that is only capable of degrading 80% of the citric acid in the media, whereas the organism of claim 1 must only be capable of degrading 50% of the citric acid.

Claims 66 and 82 are vague and indefinite because they refer to bacteria belonging to the *Oenococcus* family and the *Lactobacillus* family. There are no such organisms as there are no such family names used in the art.

Claim 79 is rendered vague and indefinite by the phrase "wherein the glucose concentration is 40 to 80 g/L and the fructose concentration is 40 to 80 g/L." In science, the term

"concentration" is used to refer to the amount of a solute in a solution. However, the claim is drawn to a dry composition. Therefore, it would be impossible to have a concentration of sugar in the composition and one would not use the units g/L to express the amount of sugar in the composition.

Claim 80 recites the limitation "the fermentable compound" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 107 is vague and indefinite because the recited method steps do not correlate to the stated goal of the claim and are thus inconsistent with the preamble of the claim. Claim 1 requires a microbial organism that has a specified set of functional characteristics. The method steps of claim 107 would not lead to production of such an organism.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Gangle whose telephone number is (571)272-1181. The examiner can normally be reached on M-F 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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/Brian J Gangle/
Examiner, Art Unit 1645

/Robert B Mondesi/
Supervisory Patent Examiner, Art Unit 1645